



This is provisional English translation of an excerpt from the original full report.

Safety Assessment Report

Soybean DP-305423-1 x MON89788 x MON87708

(Genetically Modified Foods and Feeds)

Food Safety Commission of Japan (FSCJ)

January 2018

ABSTRACT

FSCJ conducted a safety assessment of hybrid stacks of soybean, DP-305423-1 line with high contents of oleic acid x MON89788 line tolerant of glyphosate herbicide x MON87708 line tolerant of dicamba herbicide, based on the documents submitted by the applicant. Hybrid stack of MON89788 line x MON87708 line of which the safety assessments have already been completed was excluded from the assessment.

These hybrid stacks are generated through traditional cross-breeding of a line given a high oleic acid phenotype with two lines possessing phenotypes tolerant to specific herbicides, thus possess all phenotypes of the parental lines. The safety assessments of the parental lines of these hybrids were already conducted, and FSCJ concluded that the lines were judged to have no concern relevant to human health. The genetic segregation by hybridization between these lines provides the seeds that are identical to the seeds harvested from 4 lines consisting of a hybrid from 3 lines and 3 hybrids from 2 lines. FSCJ also conducted the safety assessment of 3 of these 4 lines excluding the one whose safety assessment had been completed.

These hybrid stacks are generated through traditional cross-breeding of lines possessing a phenotype tolerant to specific herbicides and a line with a phenotype of increased amount of a specific nutritional component in which metabolic pathways of the host plant are altered by inserted genes. These hybrid stacks thus fall under the category which needs the safety assessment as stipulated in “Stance on the Safety Assessment of GM Plants Generated through Cross-Breeding”¹, and FSCJ conducted the assessment based on the “Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)”².

Consequently, FSCJ concluded that hybrid stacks of soybean, DP-305423-1 line x MON89788 line x MON87708 line have no concern relevant to human health.

¹ decision of Commission dated 29 January 2004

² decision of Commission dated 29 January 2004